TRANSCRIPT OF PROCEEDINGS

IN THE MATTER OF:)
)
STAKEHOLDERS MEETINGS)
(ARBORGEN))

Pages: 1 through 40

Place: Riverdale, Maryland

Date: February 23, 2004

HERITAGE REPORTING CORPORATION

Official Reporters
1220 L Street, N.W., Suite 600
Washington, D.C. 20005-4018
(202) 628-4888
hrc@concentric.net

IN THE UNITED STATES DEPARTMENT OF AGRICULTURE

IN THE MATTER OF:)
)
STAKEHOLDERS MEETINGS)
(ARBORGEN))

Training Rooms 1 and 2
4700 River Road
Riverdale, Maryland

Monday,
February 23,2004

The parties met, pursuant to the notice, at 12:10 p.m.

BEFORE: CINDY SMITH, Deputy Administrator
Biotechnology Regulatory Services

ATTENDEES:

For USDA, Animal Plant Health Inspection Service (APHIS) and Biotechnology Regulatory Services (BRS):

REBECCA BECH
JOHN TURNER
SUSAN KOEHLER
NEIL HOFFMAN

For Arborgen:

LES PEARSON
DAWN PARKS
JAMES MANN

Participant:

MICHAEL WACH

P R O C E E D I N G S

(12:10 p.m.)

MS. SMITH: Well, good morning. We can go ahead and get started. I'm going to start with a couple of remarks. You can keep getting yourselves all settled in. We just want to make sure we have enough time to go over all the things we're going to go over.

Welcome to our stakeholders' discussion series on our upcoming environmental impact statement, our EIS, and revised Biotech regulations. The two purposes of these briefings is to first share information regarding our plans to develop an EIS and amend our plant biotech regulations, and to gather diverse and formative input which will support thoughtful and effective decisionmaking on our part in the development of our new regulations.

We want to thank you for taking time from your busy schedules to participate in this meeting and to share your thoughts with us. I am Cindy Smith, deputy administrator for the Biotechnology Regulatory Services. Joining me here we have the BRS management team, as well as a number of our colleagues from within the staff here as well.

As you likely know, we recently participated

in an interagency discussion with FDA, EPA and the White House, which concluded an agreement for us to update our plant biotech regulations. We also concluded those discussions with a general agreement of the kinds of changes that we expect to make in our regulations. But, it's important to note that there's a lot of work to be done still in flushing out the specifics of those changes.

To that end, we are very excited about the opportunity to have these informal discussions, even though they will be on the record, to gather additional input for us very early in the process on a number of issues related to the direction that we expect our regulations to take. We have a unique opportunity to have this kind of discussion, since we are not yet in the formal rulemaking phase of the process. However, our discussion will be professionally transcribed for a couple of reasons.

First, an accurate record of our discussions will facilitate our ability to make sure that we understand and we are able to refer back to the suggestions and the inputs that you have for our process. Secondly, in the interest of transparency and fairness to all stakeholders and the public who are not here, we plan to have this publicly available

and potentially put it on our Web site, so that everyone who has an interest in our upcoming process will have the opportunity to have the benefit from the discussion that we are going to have with you.

In addition, we have a notetaker here who is available to capture things on the flip charts, so if at any point you feel it's important to have it gathered and you start working on an idea or want to flush something out, we have that capability. Of course, I should emphasize that while we will be sharing information in this briefing or this discussion about what our current thinking is in BRS, there are a lot of opportunities for that thinking to evolve, both in terms of our discussion with you and the subsequent stakeholders and through the many steps of the public processes that we're about to undertake, both with writing our EIS as well as our public role.

In addition, we expect direction and insight to come from the Agency administrator, our undersecretary, the secretary of agriculture and our general counsel all through this process as well. So, we can have a very enthusiastic discussion on any aspect of our regulations today. They can sound great to all of us in the room, but there are a lot of opportunities for that thinking to continue, so I just

don't want to have any false expectations about any given aspect of our discussion. It's important for us all to keep in mind that a lot of opportunities for our thinking and what goes into our regulations to continue to evolve.

Finally, since it will be hard for you to anticipate where our final regulations will end up, what I would like to do is share with you some priorities that we have established in BRS that guide our policy and regulatory decisionmaking and operations. These are five areas of emphasis that we focus on. So you could expect to have these five areas of emphasis underpin the direction of our thinking and our results.

The first is rigorous regulation, rigorous regulation which thoroughly and appropriately evaluates and ensures safety and is supported by strong compliance and enforcement. Secondly, transparency of the regulatory process and regulatory decisionmaking to stakeholders and the public. We feel this transparency is critical to public confidence, and public confidence is critical to the success of our regulation.

Scientific-based system. Ensuring a diverse and competent scientific staff, assessing the most

current scientific knowledge and state -of-the-art technologies, and ensuring the best science is used to support regulatory decisionmaking to assure safety.

Communication, coordination and collaboration with a full range of stakeholders is another priority. Finally, international leadership, ensuring that international biotechnology standards are science-based, supporting international regulatory capacity building, and considering international implications in policy and regulatory decisions.

With that, I would like to open up the floor to hear your comments and discussion on our Federal Register notice. Since these proceedings are being transcribed, I will ask you to state your name before you talk and just remind ourselves that answering our questions and if it's the first couple times we speak, it's good for us to state our names as well. If I could just ask you to start your remarks with an acknowledgment of who is here and what organization you represent. With that, I will let you begin.

MR. MANN: Thank you, Cindy. My name is James Mann and I represent Arborgen. That's A-R-B-O-R-G-E-N. Let me introduce my team if I could. To my right, Dawn Parks. Dawn leads our external affairs, public and government affairs. To my left,

Dr. Les Pearson; Les leads our regulatory science group. I personally lead our business development efforts for Arborgen and all of our business units.

We want to thank USDA and acknowledge your allowing us to come and talk to you today. One thing we wanted to do today, Cindy, was tell you up front that we do believe the current system works. The risk-assessment approach has worked very well, but we do understand it is important always to review the process, so we completely support your review of this process. One thing we wanted to do, Cindy, today, is we could, is give you a five-minute overview of Arborgen and what Arborgen does, just so you can get some background. Dawn Parks is going to do that for us today.

MS. PARKS: Great. Thanks, James. Dawn Parks with Arborgen. Arborgen came about in the year 2000. We are actually the outgrowth of about 20 years of research and development that have been conducted on biotechnology and forest commercial trees. The partners within our organization are a joint venture and had been working on different aspects of biotechnology for quite some time.

It was really apparent at some point that it was important to bring those synergies together,

because when you are looking at the long-term nature of biotech as you apply it to trees, in terms of doing the research, it seemed more appropriate for those organizations that normally compete to come together to work on biotech and to develop a commercial product. We are still many years away from having a product that's ready to enter into the commercial mainstream, but clearly, we have been doing a lot of research and we have quite a few field tests at this point in time.

One of the neat things about the products that we're working on. You know our industry for a long time has been focused on sustainability. Sustainability is critical in terms of the forest industry. A lot of the research that has gone on for the past 50 years has really been focused on: What is the sustainable nature of forests and what are the things that we as an industry can do to improve forest sustainability?

So our researchers across the industry for more than 50 years have looked at how to -- Loblolly pine in particular, which is one of our species. How does Loblolly pine interact with the environment? We know a lot of things about all the soil interactions and the wildlife and water. Management practices over

the years have been refined so that we are actually growing a lot more wood on less land. We are also moving more and more toward the mills actually buying wood from more intensively-managed forests, as opposed to the natural forests.

So the kind of products we are developing are actually designed for use on these more intensively-managed forest operations, rather than going out and working necessarily in the natural forest. So our intent is to keep narrowing the footprint of the forest acreage that's used to supply the mills. The products, therefore, that we are working on are focused on always improving the sustainability of the forest itself. What are the different ways we can increase productivity of the forest itself and what are some of the products that we could create that could improve efficiencies in manufacturing?

So, we are working on products related to growth and we are working on products that would actually allow for the manufacturing process to be much more efficient, where you would use less chemicals or less inputs, reduced inputs in terms of making the paper or making the packaging. So those are the kinds of products that we are focused on.

We are located in Summerville, South Carolina. We now have a staff of more than 60 in the United States. We also, between the United States' operation and some of our technology providers in New Zealand and other places, have well over 90 people who are working on these products and the research. It's really been a unique venture, and there's a lot of people focused on making sure we are doing the right thing for forests and sustainability.

Anything else you guys want to add?

MR. PEARSON: Maybe just a little bit of background on the history. As you mentioned, Arborgen came into existence four years ago. We have a number of field tests. Over the years, we have had over 40 field tests. Currently, we have about 30 in the ground. We have a lot of experience, even before the formation of Arborgen, through some of the partner companies that brought technology to Arborgen, so extensive experience of dealing with issues common to the forest industry and field tests right now. So, we bring a lot of experience with field testing.

MR. MANN: Cindy, we wanted to make sure that you completely understood Arborgen. So we wanted to open up to you and your staff, if you had any specific questions for us and we wanted to then ask

you a few questions about the notification.

MS. SMITH: Okay. Do you have any questions? If not at this point, why don't we --

MR. MANN: Great. Well, that's easy. Cindy, we have taken quite a bit of time and studied the notice. I wondered if you could give us an overview of your philosophy behind the notification, expound on the notification. Give us an idea of why you came to move forward with the notification, just your basic philosophy?

MS. SMITH: I think the bottom-line idea is that while we agree with you that the current system works and has afforded the safe introduction of a number of products, at the same time the technology is really evolving. I think a driving issue that we want to address is the approaching, the advancing technology of pharmaceuticals and industrials, for example, is one area that we want to make sure that the regulatory system evolves to address unique aspects of the technology such as that.

Then there are also other things that with the Plant Protection Act of 2000, we are essentially in a position to broaden our authority and to look at a number of additional areas with respect to the products that we evaluate and the field tests that we

approve. In that ability, we want to take advantage of those authorities to better position us and to look at our system and upgrade the system to put us in a better position to address other technologies as well.

So, for example, trees are a good area for us to consider whether we currently want to look at making changes to the system to put us in a better position to be able to regulate the long-term expected growth in terms of trees, for example. So one of the things that you see in the notice is questions that would indicate we are looking at our deregulation process and building in flexibility to the deregulation process that is currently not there.

One of the types of flexibility we are talking about building in is where we can deem something as being marginally safe but there may be some remaining questions. There may be some additional data that we want to require but we don't necessarily feel like there is enough of a safety issue to stop the approval of that particular product. We could have built some flexibility into the system to allow us to approve something and then require some specific additional data to be collected after that approval for some limited period of time to address some specific scientific issue that was raised.

So one of the key things that we want to do is look at what we have learned over the course of all the experience that my colleagues here have gained through the years of regulating and ask: How would we evolve the system even further, based on what we know now and based on what we anticipate coming down the road in trying to build in flexibilities and just make sure the system is well positioned to address and manage well all of the future technologies that we expect?

Another key point I should probably mention is what we want to do is fundamentally place our emphasis and our resources where risk and science say that we should. You gain a lot of experience in some areas and there has been a lot of experience in the industry as well in some areas. So there may be enough data to suggest that some areas don't need the kind of regulation that we have provided in the past; whereas, at the same time, we would like to shift those resources over to other areas where risk would suggest that our resources are needed.

MS. PARKS: Do you want us to respond with our name each time that we speak?

THE REPORTER: I'm okay now.

MS. PARKS: Okay. Great. Thanks. When we

were looking through the notice itself, and we spent a lot of time on questions. Question 2 is really where we looked to have a little bit more clarification. We have heard different ways that this could potentially be interpreted, so I'm just curious as to whether or not you could expound a little bit more about how you see a distinction between A and B, so that when we are starting to respond to the notice, we are operating from the same place that you are.

MS. SMITH: Okay. You are talking about our risk-based categories for our multive-primitive (ph) system. So the fundamental idea there is grouping things according to the level of risk and then the regulatory decisions would be based on the level of risk there.

I think I will let John Turner speak a little bit more to the specifics of what we're thinking about acknowledging, that our thinking will be expected to continue to evolve as we go through this process.

MR. TURNER: We currently have, in a sense, a tiered system. We have two tiers. We have notifications and we have permits. Then, within the permits, there is flexibility; and there are different types of conditions and requirements we place, based

on some evaluation. Then, recently in the past year, we have established some standard conditions just for pharmaceuticals. So it's taking that idea and expanding upon it, we're thinking. We don't know how many categories yet, but, as an example, you could have three categories.

We would call them all permits rather than notifications and permits. It makes it clearer that everyone needs an acknowledgment from APHIS, no matter what they're doing, but it would be different risk categories. Also, under the expanded authority of the Plant Protection Act that Cindy talked about earlier, there may be other things that we could consider in placing them in the categories other than just plant-pest potential.

So right now, the phase that we're in is asking: Really what are those things that we should consider? How many classes should we have, and what are the risk criteria that should put something into those areas and classes?

MS. PARKS: Okay. Go ahead.

MR. MANN: No, please go ahead.

MS. PARKS: So what I am hearing you say then is that you could be looking at risk based on the product itself or on the trait or the species. Or is

there more of a lumping of things that you are considering there?

MR. TURNER: All of those things are things that are under consideration, we think of both the recipient crop and the trait, possibly the size of the test. There are a lot of things that we can consider. I would think all of those things rather than just trait or just recipient.

MR. MANN: I was going to ask something similar. John, if you were -- which is your current thinking about -- obviously, you came up with a three-tiered system in the notification. I think you mentioned a three-tiered system. Can you explain that a little bit more as to how you came up with a three-tiered system and what your thoughts are there?

MR. TURNER: Well, as I said, I don't think we're definitely going to do three. That was an example of something that we were considering. We've heard some say that if you get too many disparities, it's confusing. As I said, we currently have two. Three seemed like a good reasonable number. You can read the types of things we see, probably pharmaceuticals and industrials being a class. We see a low-risk class, which might be similar but not exactly the same as notification now. Then there's

another for those in the middle.

But beyond that, we're still open. This is an ongoing conversation and we are looking for input. So it may not be three and it may not be exactly those criteria. We are in the early stages in asking for input.

MS. BECH: John, if I might. If you look at a lot of the generic pest-risk type models and other risk-assessment models that are used, in particular within APHIS, oftentimes they categorize things as to: low, medium and high risk. So that's a very common risk-assessment type model that's used that uses those three tiers.

MS. SMITH: So since the intention here is for this to be a two-way dialogue, have you given thought or any consideration to what constitutes multilevels of risk in the criteria system?

MS. BECH: We have given a lot of thought to it. We actually have been thinking that given the way the system has operated in the past. You have looked at things on a case-by-case or a trait-by-species basis; that there is a significant amount of information available about the products that we are working on. So there's many, many years of scientific information about Loblolly pine.

So we think that there's significant enough information that would actually, based on that -- could reduce the amount of risk that's associated with our product, rather than saying since trees are not familiar at this point, that there's a lot of science behind our product. Those kind of things should be evaluated first as we start making the decisions about where in the risk categories something will fit.

So if you are really looking at the trait-by-species and what is the actual potential risk associated with the trait in the species instead of lumping all trees together, because there's a lot of different products today around trees, not that we are creating them, but between what we're working on and phytoremediation and then there's people working on restoring threatened and endangered species like the chestnut. To lump all of those trees and those traits together doesn't necessarily seem to be the appropriate way to move forward. You would want to look at actually what we're talking about putting into the environment.

MS. SMITH: Okay.

MR. PEARSON: I think I would just then endorse that because a couple of times trees have been brought up as an example. In just reemphasizing that

looking at a specific trait in the species of interest and having the risk-based categories based on them, rather than more generalized risk-based categories around a species. It's really the species and the creative interests that should be part of assessing what the risk-based categories should be.

MS. PARKS: I think that we would also agree that there are some traits, there are a lot of traits that we are working on that, with a thorough evaluation, could actually move into a very low-risk category. I think that's the important part to note.

MR. MANN: Cindy, one of the things we wanted to make sure that we were clear on before we left is what input -- or John, what input specifically are you looking for that would, from a written standpoint, that would help you to review the regulations and move forward?

MR. TURNER: Well, that's a difficult question. We are open at this time. We want to hear your concerns. We want to know from your experience where the system is working well and where you think it can be improved. Beyond that, this early in the process, we are not looking to steer the comments too much into any particular area. Different groups have different concerns and we would like to hear them.

MR. MANN: Okay.

MS. PARKS: I think that one of the things that we would like to be able to show is a level of familiarity. We often hear about some things are familiar and some things are unfamiliar. I would be curious to know when the statements are made about: we have familiarity with something or we don't have familiarity, is that experience-based, or is it a knowledge-based familiarity? Where does the definition of familiarity fall, or where does that come from?

MR. TURNER: Familiarity, in the classical sense, refers to being familiar with that trait and that species. So if we are familiar with traditional-plant breeding and that particular trait has been introduced through traditional-plant breeding, then you are in a much better position to do a risk assessment because the process shouldn't be what matters. It's the end product in biology. So that's the concept of familiarity in the traditional sense.

That being said, we also obviously have a lot more experience with traditional agricultural crops than we do with trees, but we are very open to your comments about trees and anything you can supply us with that would tell us that trees should be in one

category or the other. I think it would fall back to being familiar with the trait in that species.

MS. PARKS: Les, do you have anything?

MR. PEARSON: So in terms of thinking about the written comments that we would provide for this process, those are some of the kind of things you are looking for, some specific information on the familiarity that we have already with tree species. Are you looking for those kind of specific inputs on a particular species basis, or more broad based?

MR. TURNER: Well, I think the principle is broad based. You would be talking to what you think should be the risk criteria that would put any one thing in a particular category. You are talking about trees.

MR. PEARSON: Yes.

MR. TURNER: I think that comment could be broad based with a specific example. Anything that you particularly should consider an established category is fair game.

MR. MANN: Well, it sounds like you are very open to a lot of comments. We do have a prepared statement that I would like to read if that's okay, to make sure that we do get that on the record; and then maybe open it up to any questions, unless you have any

other questions before I read the statement?

MS. SMITH: No, go right ahead.

MR. MANN: So, as I said earlier, Arborgen supports APHIS' intent to review its regulations pertaining to the importation or statement of an environmental release of products developed through biotechnology. While the current system has been effective and protective, the Plant Protection Act gives APHIS a stronger statutory footing for its science-based oversight.

The authority provided under the PPA gives APHIS the flexibility to anticipate and keep pace with the evolving array of biotech solutions that scientists are discovering and companies are developing, such as Arborgen. The new authority will also ensure transparency, thus increasing public understanding how biotechnology is tested and regulated.

As I've stated, the current risk-assessment approaches work well. The system under which APHIS has regulated biotechnology since 1987 is effective and protective as evidenced by: the fact that more than 10,000 trials have been field tested; and more than 60 biotech products have entered into commerce without adverse effect on human health or the

environment. This approach allows for the assessment of risk on a case-by-case basis for a particular trait and a particular profit interest.

This approach is equally applicable for many of the new products under development, including products we are developing, forest trees. The environmental considerations, under which biotech products are currently evaluated, are the same environmental considerations that should be utilized to assess risk for new biotech products. For example, the effect on other floral or fauna, fitness to survive outside the highly managed agricultural environment, et cetera.

This process is fully capable of identifying products that may pose higher risk due to their potential impact on human health or the environment; and is, therefore, the appropriate process for APHIS to use in evaluating the potential risk of new and evolving products of biotechnology. However, if a tiered-risk system is to become a part of the new regulations, individual products should be assigned a particular level of risk on a case-by-case basis using sound scientific evaluation, much as you said today.

It is essential that regulations be based on the risk assessment of a particular trait in a

particular species. Assessing how a particular trait forms in a particular product is the appropriate way to assess the degree of risk for the products of biotechnology, and specifically for forest biotechnology. A trait that poses a low risk in one crop could potentially pose a higher risk in another crop. Likewise, a transformed crop may or may not pose a risk, depending on what trait is expressed in the crop.

APHIS has been employing this approach successfully since 1987 and should continue to do so. The subpage is regulations and should refrain from creating criteria for categories of products, traits and/or species to evaluate risk. We believe that some product types present a low risk to the environment, and some new product types may be perceived as having additional risk associated with them, due to the degree of scientific experience by APHIS with the product, trait or species.

As APHIS updates its regulations, it should not be a move toward broadly defining or categorizing the risk associated with new traits, species or products. Rather, APHIS should continue to address risk on a trait-by-species basis, incorporating information available from the scientific community at

large for products that have not been previously been through the regulatory process. It is through this process that APHIS can identify the risk posed by a specific product, trait or species and whether is should be considered a low risk or any other additional considerations.

Finally, familiarity can be established through science. Science should be the basis for making scientific decisions regarding safety in risk. The National Academy of Sciences describes familiarity as having enough data for regulators to make a determination of safety. Many new products that will enter into the regulatory system may be new to APHIS but have substantial underlying scientific familiarity through product performance standards based on biology of the organism trait and management practices.

Additional information about the trait is learned through scientific research, laboratory work, greenhouse experimentation and field trials. APHIS should allow applicants to use all this information to demonstrate familiarity, much as you said John.

So I guess in summary, what we would like to say: As we said, we believe the current system works, but we completely support your intent to review the regulations. But if it does have to be a tiered

system, we hope that you will support this specifically for forestry products on a case-by-case or a trait-by-species basis. When conducting the risk assessment, we hope that familiarity will not only include what you are familiar with based on scientific data, but also what is familiar in the public knowledge and what is currently available to foresters and to the USDA.

Do you have any questions?

MS. SMITH: Do you have questions?

MR. PEARSON: Maybe I could ask a question. To sum up the public statements that you've made, you have talked about the ongoing EIS process. Do you have any more understanding of how you see that progressing through this year? You talked about public meetings and the scientific advisory panels. Have you developed your ideas of how that would progress through this year again?

MS. SMITH: Actually, it has evolved a bit. I think depending on when you ask me that question, I have a slightly different answer for you, because this is the first time we've done an environmental impact statement here. It's certainly a problematic environmental impact statement, which is very significant. We just concluded a very successful two-

day program with a consultant who came in and worked with us for two days specifically on what we are planning to do and raised issues and helped us identify how we want to approach where there are some challenging things for us in terms of writing an environmental impact statement on this topic.

So we have had some outside support for that. We do plan to have public meetings. For example, our thinking at this point is the public meetings will probably come in conjunction with the proposed rule, because I think there would be more substantive information to discuss in the context of a public meeting, at the point of which we have a proposal out. So we probably wouldn't be doing public meetings before that point, general public meetings on what we're planning to do.

We are also looking at a number of scientific sessions at this point. They could be in conjunction with the EIS and/or in conjunction with the proposed rule. So we see those in the future, but we are not exactly sure as to timing at this point.

MR. MANN: Do you have a timing for the entire process?

MS. SMITH: For the entire process in terms of coming to a final rule?

MR. MANN: Yes.

MS. SMITH: We have an interest in doing this as quickly as we can do it in a way that we'll have a strong environmental impact statement and a very effective regulations when we're done. We don't see having new regulations affecting either this or the next growing season. So we envision a process of a draft environmental impact statement, a final environmental impact statement, a draft or a proposal, a final rule taking probably a couple of years to complete, which would be in and of itself an extraordinarily fast time frame for similar kinds of initiatives.

So this is a priority for APHIS. We're putting all the resources into it that we can. We plan doing this as quickly as we can, but we also won't compromise the integrity of what we're doing by moving too quickly. So I think as we go in, and particularly as we see the best of the comments that we get during this initial scoping process, we will have a better sense of what the range of issues are, the additional issues that the public can state.

Or as you're raising them, we need to be addressing them. We will have a better sense the further we go through the process of what our timeline

will be.

MS. PARKS: Will there be any opportunity for people to provide you with names of people who could be valuable in terms of scientific input to some of your panels? I could envision that we could write several books for you on forestry, just because there's just a ton of information out there. But it might be valuable for you to have some specific people you could go to, or you could learn more from an academic perspective about the crops that we are working with to help you formulate your decisions.

MS. SMITH: Sure. That would be very constructive for us. I think that any point in the process we would be open to you providing us those sort of things; and then we will also look at what we want to do to more systematically, go out and look for things that individuals, depending on what it is we're going to be doing in the process.

MR. MANN: Cindy, would you be open to an audience with you or John between now and the time the written comments are due --

MS. SMITH: Sure.

MR. MANN: -- if we had additional questions or if some additional -- probably more about additional questions. That would probably be when we

would need an audience with you.

MS. SMITH: I think we are willing to have ongoing discussions. I think we will see that as very important to what we're doing. What we will need to do is just kind of factor in how many of those requests we get and whether we can just take them on a case-by-case basis, because there's not a lot, or if there are a lot, maybe setting up some additional series of discussions. But certainly, if you will express the interest, then we can see where we are and address that.

MS. PARKS: I know that your comment period ends on March 23rd. Is your plan after that, then you will actually go right into the EIS process, or will you still be taking information after that?

MS. SMITH: We are in the EIS process now and we have already begun some initial very good work. Then we will use those comments to more fully inform what we are going to do in terms of the draft EIS, but then we will still have additional comment periods for both the EIS and for the rule to formally solicit public comments. Then we will also be open wherever it fits into the process appropriately for additional comments.

In other words, once we've come out with the

proposed rule, then there are specific restrictions on our ability to speak just with one group and not make it a public process. But until we come out with that proposed rule, we are in a good position to have a lot of good dialogue.

MR. PEARSON: I guess as I asked about the EIS process and you talked about having proposed changes to the rules, does APHIS envision that that would be across all of these different areas, or would there be a chance to interact on specific issues among your 11 questions?

MS. SMITH: I'm sorry. Ask me again?

MR. PEARSON: So when you said that there would be additional public comment when new proposed rules came out.

MS. SMITH: Okay.

MR. PEARSON: So those proposed rules would cover all of these areas, or would there be specific questions that you would be looking to implement?

MS. SMITH: I would envision that when we come out with the proposed rule, it will affect everything that we regulate currently in terms of genetically-engineered plants and other organisms that currently pose a plant-pest risk. But, under the new regulations, it would also be anything that could pose

a noxious-weed risk or certainly as a biological control agent. Potentially, we are looking at those two areas. So the comments, at that point, would be for anything across any of those areas.

I would imagine when we issue our proposed rule, we may have specific questions in additional areas of about emphasis, but we would entertain comments on the complete breadth of the rule at that point.

MS. PARKS: I just would like to go back to something we had talked about a little bit earlier that we didn't explore very much. I was just wondering if you could comment a little bit more about Question 3. We didn't really talk about Question 3 in the notice. We just would like to know if you could give us some more thoughts about the notion of deregulating and potentially requiring some additional information.

I think you referred to it as minor-unresolved risks. But we are trying to get a sense about what are those kinds of risks. Is it really risk, or just looking for additional information?

MR. TURNER: It would have to be a risk that we could define scientifically. We certainly are not proposing monitoring for the sake of monitoring ever,

or monitoring things where there's no reason to believe there would be in effect. It would only be in cases where there was an identified risk, even monitoring and the types of monitoring that would be done would be tied back to risk and that wouldn't be for every product. That would be for some products.

MS. PARKS: So it would be based on probably the actual product. It is not going to be a generalized question. Okay.

MS. SMITH: Do you have any other questions?

MR. MANN: Cindy, I want to, unless you have any other questions --

MS. SMITH: Actually, I do.

MR. MANN: Good.

MS. SMITH: Did you want to ask your question?

MR. MANN: It's up to you. You go first.

MS. SMITH: Okay. Do tree crops raise unique biotechnological questions, and should tree crops be given special regulatory consideration? We would appreciate hearing your thoughts on these questions.

MS. PARKS: Can you say it again?

MS. SMITH: Why don't I just give you this.

MS. PARKS: Okay.

MS. SMITH: I will just give you the card.

MS. PARKS: Okay. I'm not sure what you mean by a unique biotechnological question. Can you say a little bit more about that?

MR. WACH: This is Mike Wach speaking. I have read The Commerce Bioresearch Institute of January about tree crops that they raised and they shouldn't be treated like soy beans for example because soy beans -- Do you agree with that? Oh, I am not speaking loud enough?

MS. SMITH: If you could come up and talk into the microphone, that makes it easier for her. I'm sorry. I can share it with you.

MR. WACH: Other researchers, who have worked with some engineered trees, have said that they feel that trees are different from soybeans or corn or wheat, when you deal with working with them as a research species or a research host. I am curious if you feel the same way, that you look at trees as different from annual seed crops, for instance; and if we should treat them differently in some way that would either make your work easier or give you a greater amount of guidance in how you do your work?

MS. PARKS: Does anybody want to say from a biological perspective?

MR. PEARSON: Yes. I guess one of the points we are trying to make is always going back to the specific species and the trait that we are looking at. So simply because there are obviously different biological issues to look at with trees that it would be different from soybeans. But you have to look at those in context of the trait that's being engineered.

So I think we would caution against broadly lumping trees into a specific category. You always have to go and look at the biology of the species but then think about how the trait interacts with that.

MS. PARKS: To think of the bottom line: We don't think that trees in general need to be treated separately. You would have to look first at the species to see if there's anything about that species that would cause you to want to treat it separately.

MR. WACH: What about the time frames? I don't know anything about working with them. I used to work with agri crops when I did research in this area. I know nothing about the time frames of dealing with trees as a species. I just worked with several different species. I assume they're a longer time frame.

MR. PEARSON: We all are dealing with multiple-tiered tests, so we envision that we would

have several years worth of data. There are standards that are used within the tree-improvement industry right now that I think are a good guidance on what kind of data would be appropriate. So we expect that, certainly multiple-tiered tests -- that's the basis of the species we're interested in, so that isn't asked. It may be a little bit different, but that would be true of other perennial species also.

MR. WACH: So with an annual crop, for instance corn, you have data that you collect throughout the growing season. At the end of the growing season, you have a year's worth of data. With a tree species, the same conceptual amount of data may take several years to accumulate.

MR. PEARSON: I think we would be guided by some of the standards that are common within tree improvement. There's a lot of history in tree improvement over the years, so I think that would be our standards and we could look at those as guidelines.

MS. PARKS: The industry already makes decisions at certain key points early in the life cycle of a tree and makes commercial decisions as to what they're going to put it finally on, because we know nothing about the biology of the tree that you

can tell, at a certain age of a tree, whether or not it's going to be performing to your standard. And we think, being that we are working within pathways that are already utilized by the tree, we can predict, at a very early age, how that will function over the long term.

MR. PEARSON: So that, I think, gets back to John Turner, your point that some of the biochemical pathways that would be looked at in trees are very familiar. So we're looking at traits as you suggested, John, that may also be approached through a breeding strategy. That would be a familiar trait-by-species combination that we should be looking at assessing it in that way.

MS. PARKS: Thank you.

MR. MANN: Thank you for the question.

MS. PARKS: Any other questions?

MS. KOEHLER: Are there areas where you would like to see regulatory flexibility with regards to the types of products that you are working on, either in terms of -- for example, there's a question in here about container requirements, moving to maybe a performance-based standard for container requirements, or maybe regulatory flexibility in regards to interstate movement permits or whatnot.

Are there are specific aspects of your research that you feel that warrant regulatory flexibility?

MR. PEARSON: That's a very good question. Yes, there are. I think we would probably look to address those more in our written comments because we didn't come prepared to talk about that. But I think that is one area that we would hope to see some regulatory flexibility. But in terms of specific recommendations, I think we would probably develop that more for our written comments.

MS. SMITH: Any others? Okay.

MR. MANN: Cindy, thank you for your good job. Thank you for your time today. We appreciate the opportunity to come and talk to you today. I've already given you our thoughts and hope again that you understand that we do believe the system is working, but we completely support your review of the process, and we hope to have further communication with you over the coming months as you work through the system.

Thank you again. Thanks to all the people here today.

MS. SMITH: Thank you. We really appreciate you taking the time to join us today. This is very useful for us, and we look forward to continuing this

discussion in the future.

MR. MANN: Thank you.

ALL: Thanks.

(Whereupon, at 1:02 p.m, the meeting was concluded.)

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REPORTER'S CERTIFICATE

TITLE: Stakeholders Meetings (Arborgen)

DATE: February 23, 2004

LOCATION: Riverdale, Maryland

I hereby certify that the proceedings and evidence are contained fully and accurately on the tapes and notes reported by me at the hearing in the above case before the United States Department of Agriculture.

Date: February 23, 2004

Renee Miskell

Official Reporter
Heritage Reporting Corporation
Suite 600
1220 L Street, N.W.
Washington, D.C. 20005-4018